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In re Application of :
YAN et al. :
Serial No.: 09/908,943 :Petition Decision
Filed: July 19, 2001 :
Attorney Docket No.: 29915/0028 IA.US :

This decision is in response to the petition under 37 CFR 1. 181 and 1.144, filed March 15, 2004, requesting withdrawal of an improper restriction requirement. The decision mailed 14 October 2004 (as determined by PTO PALM records, although the petition decision itself apparently did not contain a mail room date stamped on the action) has been vacated as premature. The confusion arising from the incomplete decision inadvertently mailed 14 October 2004 and the delay in acting upon this petition are regretted.

BACKGROUND

A review of the file history shows that this application was filed on July 19, 2001, and contained claims 1-82. In a first Office action, mailed September 19, 2002, the examiner set forth a restriction requirement under 35 U.S.C. 121, as follows:

> Groups 1-52, claims 1-20, 28-35, drawn to a peptide of SEQ ID NO: 5-18, 120, 133-138, 141, 143-145, 147-169, 190-193, respectively, classified in class 530, subclass 327.
>
> Groups 53-55, claims 21-27, drawn to a peptide wherein P2 is N, S or D, respectively, classified in class 530, subclass 330.
>
> Groups 56-58, claims 21-27, drawn to a peptide wherein P1 is Y, L or Nle, respectively, classified in class 530, subclass 330.
>
> Groups 59-61, claims 21-27, drawn to a peptide wherein P1' is E, A or D, respectively, classified in class 530, subclass 330.

Groups 62-63, claims 21-27, drawn to a peptide wherein P2' is A or V, classified in class 530, subclass 330.

Groups 64-126, claims 36-42 and 52-54, drawn to a polynucleotide that encodes the polypeptide of claims 1-35, a vector, a host cell and a method of producing a substrate for a B-secretase assay, classified in class 435, subclass 320.1 and 252.3 and class 536, subclass 232.1. The groups 64-126 correspond to groups 1-63.

Groups 127-189, claims 43-50, drawn to a method for assaying for modulators of B- secretase activity, a method of inhibiting B-secretase activity in vivo, classified in class 435, subclass 23. The groups 127-189 correspond to groups 1-63.

Groups 190-252, claims 51 and 55-57, drawn to a method of inhibiting the B-secretase activity in vivo/ comprising administering a modulator according to claim 50, a pharmaceutical composition comprising a modulator, a method of treating a disease comprising administering the pharmaceutical composition and the use of a modulator to treat Alzheimer's disease, classified in various classes and subclasses depending upon what the inhibitor is. The groups 190-252 correspond to groups 1-63.

Groups 253-315, claims 58-64, and 66-67, drawn to a method for identifying agents that inhibit Asp2 aspartyl protease and a method of identifying agents that modulate Asp2 aspartyl protease, classified in class 435, subclass 219. The groups 252-315 correspond to groups 1-63.

Groups 316-378, claims 65 and 68-69, drawn to a method of treating Alzheimer's disease comprising using an inhibitor of Hu-Asp2, classified in various classes and subclasses depending upon the identity of the inhibitor. The groups 316-378 correspond to groups 1-63.

Groups 379-441, claims 70-72, drawn to a kit for performing a B-secretase assay, classified in class 435, subclass 23. The groups 379-441 correspond to groups 1-63.

Group 442, claims 73-82, drawn to a peptide, classified in class 530, subclass 328, 327, 326, and 324.

The examiner provided the following reasons for the Restriction Requirement:

Groups 1-63 and 64-126 are drawn to completely different chemical compounds that are patentably distinct. Groups 1-63 and 442 are drawn to different structural peptides and are patentably distinct.

Inventions 1-63 and 127-189 are related as product and process of use, and that, in the instant case, the product as claimed can be used in a materially different process such as in the methods of groups 190-252, 253-315, 316-378, and in the kit or groups of 379-441.

Inventions 1-63 and 190-252 are related as product and process of use, and that, in the instant case, the product as claimed can be used in a materially different process such as in the methods of groups 127-189, 253-315, 316-378, and in the kit or groups of 379-441.

Inventions 1-63 and 253-315 are related as product and process of use, and that, in the instant case, the product as claimed can be used in a materially different process such as in the methods of groups 127-189, 190-252, 316-378, and the kit or groups of 379-441.

Inventions 1-63 and 316-378 are related as product and process of use, and that, in the instant case, the product as claimed can be used in a materially different process such as in the methods of groups 127-189, 190-252, 316-378, and the kit or groups of 379-441.

Inventions 379-441 are drawn to a product (kit) that is patentably distinct and the products of groups 1-63 and 64-126.

Claim 33 is presumed to be drawn to a polypeptide instead of a fusion protein, since there is no antecedent basis for fusion protein in claim 28-32.

The examiner argued that the restriction is proper because the inventions are distinct for the reasons above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter.

Applicants replied on November 19, 2002, electing Group 56, claims 21-27, drawn to a peptide of a generic sequence in which P1 is Y, with traverse, specifically arguing the examiner has failed to articulate a proper restriction requirement and that the invention should not be restricted 442 ways; and that the examiner has simply failed to establish that there is a serious burden to examine all of the claims. Applicants further argued that restriction practice under 35 USC 121 allows the Commissioner discretion to require restriction between two or more independent and distinct" inventions and that in the present invention, the claims are not independent. For example, the peptide/polypeptide subject matter of claims 1-35 and 73-82 is directly connected in design (i.e. the protein or peptide sequences all comprise a scissile bond that is cleaved by a human aspartyl protease), they operate in the same manner (i.e. the peptides are cleaved by human apartyl protease), and have the same effect (i.e. mimic the effects of wild-type substrate for human aspartyl protease).

The examiner mailed a non-Final Office action on February 21, 2003, acknowledging applicants' election of Group 56, claims 2 1-27, wherein P1 is Y, and making the restriction requirement final. The examiner responded to the traversal by indicating, for example that examining groups 1-35 and 73-82, as one group, as suggested by applicants would require the search of 52 different specific sequences as well as claims 1 and 2 1 that are drawn to a multitude of different peptides. Each of the peptides of claims 1-35 and 73-82 are structurally different and therefore properly restricted. The examiner further states that the search of 52 different sequences would, in itself, be an unreasonable burden upon the examiner, not taking into account the search of claims 1 and 21, which read on numerous embodiments.

Applicants replied on March 15, 2004 by filing this petition. Applicants filed a full reply to the Office action on May 21, 2003.

DISCUSSION

The application, file history and petition have been considered carefully.

The petition raises the following concerns (A)-(E), each of which will be addressed in turn:

(A) The peptide claims define a genus of peptide substrates using the formula: P2P1-P1'P2' adopting the nomenclature of Schechter and Berger (Biochem. Biophys. Res. Commun. 27:15741967) and Biochem. Biophys. Res. Commun. 32:898 (1968), in which the amino acid residues in the peptide substrate that undergo the cleavage are defined as P1 . .. Pn moving from the scissile bond toward the N-terminus and P1, . . . Pn' moving from the scissile bond toward the C-terminus. (See specification paragraph bridging pages 18 and 19).

The peptides defined by the foregoing formula share common structural features as evident from the genus defined by a single chemical formula wherein each amino acid position near the scissile bond has specified characteristics. Likewise, the peptides share a common functionality due to their common structure, as evinced by the fact that the peptides all serve as peptide substrates that are recognized and cleaved between residue Pl and P1' by a particular human aspartyl protease.

(B) Claim 1 as filed embraces a number of species that do not fall within restriction groups 1-52 and that were not explicitly assigned by the examiner to any other restriction group.

The restriction requirement is further facially defective because it fails to clearly assign the entirety of the claimed subject matter to individual groups. For example, original claim 1 was split into fifty-two distinct groups which each define a particular peptide species, yet the claim 1 actually encompasses more than 52 species.

(C) An exemplary peptide disclosed in the specification and referenced in at least original claims 20 and 73-78 is SEQ ID NO: 152, which has the following amino acid sequence: SEISY-EVEFR. Applying the Schechter and Berger nomenclature 2), SEQ ID NO: l52 is written as P5P4P3P2P1—P1'P2'P3'P4'P5', wherein P5 is S; P4 is E, P3 is I, P2 is S; P1 is Y, Pl' is E, P2' is V; P3' is E, P4' is F, and P5' is R.

A peptide satisfying SEQ ID N0: l52 falls into at least six different restriction groups as defined by the examiner:

(a) Group 31 defines an allegedly independent and distinct group with the sequence SEQ ID NO: 152,

(b) Group 54 defines an allegedly independent and distinct group with the requirement that P2 be S. In SEQ ID NO: 152, P2 is S. Thus, a peptide comprising SEQ ID NO: 152 falls within Group 54.

(c) Group 56 defines an allegedly independent and distinct group with the requirement that Pl be Y. In SEQ ID NO: 152, P1 is Y. Thus, a peptide comprising SEQ ID NO 152 falls within Group 56.

(d) Group 59 defines an allegedly independent and distinct group with the requirement that Pl' be E. In SEQ ID NO: 152, Pl. is E. Thus, a peptide comprising SEQ ID NO: 152 falls within Group 59.

(e) Group 63 defines an allegedly independent and distinct group with the requirement that P2' be V. In SEQ ID NO: 152, P2. is V. Thus, a peptide comprising SEQ ID NO: 152 falls within Group 63.

(f) Group 442 includes claim 73, which explicitly recites SEQ ID NO: 152.

Numerous other peptides of the invention besides SEQ ID NO: 152 , fall within two or more restriction groups because the groups do not define independent or distinct inventions.

By obvious extension, the analysis in paragraph 8 (C, above) is equally applicable to restriction groups 64-126, which define polynucleotide subject matter, restriction groups 127-378, which define various method subject matter; and groups 379-441, directed to kits. In each instance, the Examiner used the alleged independence or distinctness of the peptide groups 1-63 as a basis for restricting the other categories of subject matter. In fact, groups 127-441 were not individually defined, except to specify that they corresponded to be peptide groups 1-63. As exemplified in claim 21 as filed, P1 may be selected from the group consisting of Y, L, and Nle; P1' may be selected from the group consisting of E, A and D.

It is both axiomatic and required by the patent statute that claims only be restricted when they define independent and distinct inventions. The current restriction requirement is defective insofar as it specifies 442 overlapping groups such that individual species of the invention fall within multiple groups. It is impossible for restriction groups to be "independent" or "distinct" from one another when the same polypeptide falls within at least six of the groups.

(D) According to the Patent Office guidelines set forth in the MPEP, restriction practice under 35 U.S.C. 121 allows the Commissioner discretion to require restriction between two or more "independent and distinct" inventions (See M.P.E.P. 802.01 defining independent and distinct). M.P.E.P. 802.01 defines "independent" in relation to this practice, to mean:

> that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, for example: (1) species under a genus which species are not usable together as disclosed', or (2) process and apparatus incapable of being used in practicing the process."

As stated in MPEP 806.04(a), the rules provide that a reasonable number of species may still be claimed in one application. Moreover, the MPEP requires that "where there is a relationship disclosed between the species, such disclosed relation must be discussed and reasons advanced leading to the conclusion that the disclosed relation does not prevent restriction, in order to establish the propriety of restriction." MPEP 808.0l(a). Even when restriction is proper, the MPEP requires that the Examiner should clearly identify each of the disclosed species to which claims are restricted and identify the distinguishing characteristics of species. See, e.g., MPEP 809.02(a).

(E) The petition then proposes the following Groups:

> Group I: An isolated peptide defined by the formula P2P1-Pl'P2', wherein P1-P1' is Y-E; kits comprising the same; polynucleotides encoding the same and methods of making or using the same
>
> Group II: An isolated peptide defined by the formula P2P1-P1'P2', wherein P1-P1' is Y-A,' kits comprising the same; polynucleotides encoding the same and methods of making or using the same;
>
> Group III: An isolated peptide defined by the formula P2P1-Pl'P2', wherein P1-P1' is Y-D; kits comprising the same; polynucleotides encoding the same and methods of making or using the same;
>
> Group IV: An isolated peptide defined by the formula P2P1-P1'P2', wherein P1-P1' is L-E; kits comprising the same; polynucleotides encoding the same and methods of making or using the same;
>
> Group V: An isolated peptide defined by the formula P2P1-P1',P2', wherein Pl-P1' is L-A; kits comprising the same; polynucleotides encoding the same and methods of making or using the same;
>
> Group VI: An isolated peptide defined by the formula P2P1-P1'P2', wherein P1-P1' is L-D; kits comprising the same; polynucleotides encoding the same and methods of making or using the same;

Group VII: An isolated peptide defined by the formula P2Pl-P1'P2', wherein Pl-P1' is Nle-E; kits comprising the same; polynucleotides encoding the same and methods of making or using the same;

Group VIII: An isolated peptide defined by the formula P2P1-P1'P2', wherein P1-P1' is Nle-A; kits comprising the same; polynucleotides encoding the same and methods of making or using the same;

Group lX: An isolated peptide defined by the formula P2P1-Pl'P2', wherein P1-P1' is N1e-D; kits comprising the same; polynucleotides encoding the same and methods of making or using the same.

Representative claims are set forth below:

From original Groups 1-52

1. An isolated peptide comprising a sequence of at least four amino acids defined by formula P2Pl-P1'P2' wherein
P2 is a charged amino acid, a polar amino acid, or an aliphatic amino acid but is not an aromatic amino acid;
Pl is an aromatic amino acid or an aliphatic amino acid but not a polar amino acid or a charged amino acid;
P1' is a charged amino acid, or aliphatic amino acid, or a polar amino acid but is not an aromatic amino acid',
P2' is an uncharged aliphatic polar amino acid or an aromatic amino acid; and
wherein said peptide is cleaved between P1 and P1' by a human aspartyl protease encoded by the nucleic acid sequence of SEQ ID NO:1 or SEQ ID NO:3 and said peptide does not comprise the corresponding P2P1-P1'P2, portion of amino acid sequences depicted in SEQ ID NO:19; SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:26; SEQ ID N0:27; SEQ ID NO:28; SEQ ID NO:31; SEQ ID NO:32; SEQ ID NO:33; SEQ ID NO:34; SEQ ID NO:35, SEQ ID NO:36; SEQ ID NO:37; SEQ ID NO:38; SEQ ID NO:39; or SEQ ID NO:40.

From original Groups 127-189

49. The method claim of any of claims 43-48, further comprising a step of treating Alzheimer 's Disease with an agent identified as an inhibitor of Hu-Asp2.

From original Groups 316-378

65. A method according to 58 or 64, further comprising a step of treating Alzheimer's Disease with an agent identified as an inhibitor of Hu-Asp2.

From original Groups 379-441:

70. A kit for performing a beta secretase assay comprising a beta secretase substrate comprising a peptide according to any of claims 1 through 27 and a beta secretase enzyme.

Under (A), the petition argues that the peptides share a common function and a common structure. MPEP 803.02, which is directed at Markush groups, specifies when compounds claimed in the alternative may be considered for species election, and states:

> If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions.

MPEP 803.02 goes on to specify when elements in a Markush may be considered to have "unity of invention" as defined by In re Harnisch.

> Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Four randomly selected peptides recited in the Markush Group of claim 20 are set forth below. Common structure among the four or even between any two of the four is not apparent.

SEQ ID No 6
Lys Val Glu Ala Asn Tyr Glu Val Glu Gly Glu Arg Cys Lys Lys

SEQ ID No 11
Ile Ile Lys Met Asp Asn Phe Gly

SEQ ID No 13
Thr His Gly Phe Gln Leu Xaa His

SEQ ID No 137
Lys Thr Ile Ser Leu Asp Val Glu Pro Ser

The Markush Group of claim 20 specifies structure for the combination of P2P1-P1'P2' and recites about 50 peptide sequences. The number "fifty" is not considered as few in number. The sequences recited in claim 20 are not so closely related as to be examined without undue burden.

For these reasons, concurrent examination of the 50-odd sequences in claim 20 is not required by the first sentence of MPEP 803.02.

While the compounds in this invention share a common utility, there is no shared common structure essential for that utility. For these reasons, the peptides are not considered as species eligible for treatment under specific practice and the petition's concern (A) is not persuasive.

Concerning (B), (C) and (D), applicants are correct that the restriction requirement groupings are incorrect and the inventions are not clearly identified. A review of the restriction requirement prompted by the petition identified the following problems with the way in which the groups are set forth:

(1) some inventions are not placed in any group
(2) same invention is encompassed by multiple groups
(3) linking claims not identified or properly treated.

The Groups are correctly set forth as follows:

Groups 1-2940, claims 1-23, 25-35, 70-101, drawn to a peptide which has P2P1-P1'P2' wherein P2, P1, P1' and P2' are each selected from the amino acid residues set forth in claims 6, 7, 8 and 9, respectively. Please see Table 1, below for further explanation of how each peptide invention is defined. Each combination represents one invention. The peptide groups are classified in class 530, subclass 327.

Groups 2941-5,430 claims 36-42 and 52-54, drawn to a polynucleotide that encodes one of the polypeptides of Groups 1-2940, a vector, a host cell and a method of producing a substrate for a B-secretase assay, classified in class 435, subclass 320.1 and 252.3 and class 536, subclass 232. 1.

Groups 5,430-8,370, claims 43-48, 50, 58-64, and 66-67, drawn to a method for assaying for modulators of B- secretase activity, identifying agents that inhibit Asp2 aspartyl protease or modulate Asp2 aspartyl protease of Groups 1-2940, classified in class 435, subclass 23.

Groups 8,370-11,310, claims 49, 51, 55-57, 65, 68-69 drawn to a method of inhibiting the B-secretase activity in vivo comprising administering a modulator of Groups 1-2940, a pharmaceutical composition comprising a modulator, a method of treating a disease comprising administering the pharmaceutical composition and the use of a modulator to treat Alzheimer's disease, classified in various classes and subclasses depending upon what the inhibitor is.

Table 1. Peptide inventions defined as a combination of one of each of P2, P1, P1' and P2'.

P2	P1	P1'	P2'
Claim 6	Claim 7	Claim 8	Claim 9
N	Y	E	V
L	L	A	A
K	M	D	N
S	Nle	M	T
G	F	Q	L
T	H	S	F
D		G	S
A			
Q			
E			

The number of inventions has been calculated as 2,940, by multiplying each of 10 choices for P2, 6 choices for P1, 7 choices for P1', and 7 choices for P2'.

When selecting a combination defining P2P1-P1'P2', applicants are under obligation to specify which claims and which sequences read upon the selected invention.

For example, if applicants elect P2P1-P1'P2' as SY-EV, applicants should point out that this peptide is encompassed by on SEQ ID NO 152, 158 and191 and claims 96, 97, 99, to name a few. (It is noted that other sequences and claims may also encompass this invention, but for purpose of explanation in this petition decision, the Office will not continue the analysis through the entire set of claims or list of sequences.)

The restriction requirement is proper for the following reasons:

The peptides, the polynucleotides and inhibitors of are structurally, functionally and patentably distinct molecules. Each of the peptides as defined in Table 1 are structurally and patentably distinct molecules. Each of the polynucleotides are structurally and patentably distinct molecules. The methods are patentably distinct from the products in view of the fact that more than one materially different product may be used in the method and more than one materially different method may be practice by each product. For example, each product can be used for either screening method to identify inhibitors or immunological method to raise antibodies. It would require undue burden to examine two or more inventions in view of the structural divergence of the peptides and polynucleotides and in view of the different classification. For example, a search for peptide having SEQ ID No 6 would not identify prior art which reads upon peptide having SEQ ID No 137 and vice versa. The restriction requirement is proper because the inventions are shown as distinct for the reason set forth above and have acquired a different status in the art as shown by their divergent classification and recognized divergent subject matter.

Concerning (B), Applicants are correct that the original restriction requirement failed to identify and properly treat linking claims, which describes the inventions in generic terms and encompass (1) some or all of the inventions in claims 1-19, 21, 23, 25-35, 70-72, 83-95 and (2) also include inventions directed at other isolated peptides encompassed by but not specifically listed in the claims. Indeed the groupings set forth in the original restriction requirement do not specifically

account for all the possible combination of peptides in claim 1. Linking claim practice is the correct way to handle this breadth of claims, as follows.

The examiner should have included the following paragraph in the Restriction Requirement and Office actions to identify the linking claims:

> Claims 1-19, 21, 23, 25-35, 70-72, 83-95 link(s) peptide inventions of recited in the combination of claims 6-9, as set forth above.
> Polynucleotide claims which refer to peptides in Claims 1-19, 21, 23, 25-35, 70-72, 83-95 link(s) polynucleotide inventions.
> Assay method claims which refer to peptides in Claims 1-19, 21, 23, 25-35, 70-72, 83-95 link(s) the assay method inventions.
> Administration method claims which refer to the peptides in Claims 1-19, 21, 23, 25-35, 70-72, 83-95 link(s) administration method inventions.
>
> The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Additionally, the examiner erred in limiting the examination of the generic linking claims to the elected invention. Applicants are correct that they deserve examination of the generic linking claims along with the elected invention.

MPEP 809.04 states that

> Where the requirement for restriction in an application is predicated upon the nonallowability of generic or other type of linking claims, applicant is entitled to retain in the case claims to the nonelected invention or inventions.
>
> If a linking claim is allowed, the examiner must thereafter examine species if the linking claim is generic thereto, or he or she must examine the claims to the nonelected inventions that are linked to the elected invention by such allowed linking claim.

The restriction requirement between the products and the kits comprising the products is improper and has been withdrawn. The corresponding kit will be examined along with any elected product.

The restriction requirement between the methods of claims 49 and 65 comprising a step of treating Alzheimer's Disease with an agent identified as an inhibitor of Hu-Asp2 is improper as it contains subject which overlaps in scope.

Concerning (E), applicants' proposed groups I-IX are not are acceptable for one of the same reasons that the Examiner's Restriction Requirement was not acceptable. The Groups I-IX fail to account for all the claimed subject matter. For example, P1 as defined in Groups I-IX can be only Y or L, however, current claims also specify that P1 could be aromatic or aliphatic (claim 1) or M or Nle or F or H (claim 6), etc.

DECISION

The petition under 37 CFR 1.144 filed 15 March, 2004 is **GRANTED-in-PART** as follows:

The restriction requirement mailed 19 September 2002 has been withdrawn and replaced with the restriction requirement contained in this petition decision.

Applicants will be given ONE MONTH to respond to this restriction requirement and select both
(1) a particular the type of invention (protein, polypeptide, assay method or method of administration) and
(2) particular peptide used in or referred to by the invention, by specifying residues for P2P1-P1'P2' as recited in claims 6-9, respectively. Applicants must also inform the Office of which claims and which sequences read upon the elected invention.

Upon election, the application will be forwarded to a different examiner in art unit 1639 for preparation of an Office action which is consistent with this petition decision and which follows linking claim practice with regard to the generic claim and which is responsive to the election and to the amendment and response filed 19 March 2004.

Any request for reconsideration of this petition decision must be filed within 2 (two) months of mail date of this petition.

There was no fee required for the filing of this petition.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-872-9306.

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